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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/095,536	06/10/1998	JOHN A. KINK	OPHD-03282	9749

23535 7590 11/19/2002

MEDLEN & CARROLL, LLP
101 HOWARD STREET
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EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 11/19/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/095,536

Applicant(s)

KINK, JOHN A.

Examiner

Joseph F Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-12 and 15-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-12, 15-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Formal Matters

Claims 1-6 and 19-33 were cancelled in Paper No. 25, 9/16/2002. Claims 7-12, 15-18 are pending and under consideration.

Response to Amendment

The rejection of the cancelled claims are moot and thus withdrawn.

The rejection of claims 7-15 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,888,511 (Skurkovich et al.) has been withdrawn.

The rejection of claims 7-12, 15-18 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,888,511 (Skurkovich et al.) in view of U.S. Patent No. 5,585,098 (Coleman et al.) has been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7-12, 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. patent No. 5,723,120 (Brakenhoff et al.) in view of U.S. Patent No. 5,888,511 (Skurkovich et al.) and further in view of U.S. Patent No. 5,585,098 (Coleman et al.).

The '120 patent discloses a method for treating IL-6 related diseases, said method comprising administering to a patient in need of such treatment a pharmaceutical composition containing an amount of an IL-6 receptor antagonist effective for treating sepsis and a pharmaceutically acceptable carrier (column 3, lines 14-20). The '120 patent further discloses that other agents which may be combined with IL-6 receptor antagonists include monoclonal antibodies directed to cytokines involved in the sepsis pathway, such as antibodies directed to IL-6, and antibodies directed to TNF (column 12, lines 44-50). Thus, the '120 patent discloses methods of treating patients with sepsis with therapeutic compositions comprising anti-TNF and anti-IL-6 antibodies.

The '120 patent does not disclose routes of administration of the therapeutic composition comprising anti-IL-6 and anti-TNF antibodies. U.S. Patent No. 5,888,511 discloses methods of treating autoimmune diseases by administration of antibodies to IL-6 in addition to anti-TNF antibodies (column 5, lines 41-50). Compositions comprising anti-IL-6 antibodies and antibody to TNF are claimed in claim 3, column 30, lines 10-21. The '511 patent discloses methods of methods of administration including intravenously, orally and parenterally at column 18, lines 17-30. The '511 patent at column 15, lines 47-49 disclose the production of (polyclonal) antibodies in mice, rabbits and humans, for use in the disclosed methods.

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U.S. Patent No. 5,888,511 does not disclose the use on antibodies derived from avian sources. U.S. Patent No. 5,585,098 discloses the use of polyclonal antibodies prepared from chicken eggs to neutralize systemic pathogens in mammals (column 4, lines 30-50). U.S. Patent No. 5,585,098 further discloses the advantages of using polyclonal antibodies derived from chicken eggs, including, *inter alia*, Chicken antibodies do not react with mammalian complement, Fc receptors, protein A or protein G. Yolk antibodies show great acid and heat resistance. Extraction of yolk antibodies can be performed even on a large scale without costly investment. Concentrating the antibody from egg yolk is a relatively straightforward process. The antibody is not harmed by pasteurization. The FDA regards egg antibody as a food rather than a drug and has granted GRAS (generally accepted as safe) status thereto (column 5, line 61 to column 6 line 2).

Therefore, it would have been obvious to one of skill in the art at the time the invention was made to practice a method of treating patients with sepsis with therapeutic compositions comprising anti-TNF and anti-IL-6 antibodies which are avian in source. The motivation is provided in the '120 patent which discloses that when used to treat sepsis, IL-6 receptor antagonists may be given in combination with other agents which would be effective to treat sepsis to attenuate sepsis or septic shock (column 12 lines 1-11). The motivation to use antibodies derived from avian sources is provided in the '098 patent which discloses the advantages of egg yolk antibodies (column 5 lines 62-67).

Conclusion

No claim is allowed.

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Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245.

The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
November 14, 2002